

Serial No.: 10/825,183

### **REMARKS**

Claims 1-28 are currently pending in the application. By this amendment, claims 1 and 26 are amended for the Examiner's consideration. The above amendments do not add new matter to the application and are fully supported by the specification. For example, support for the amendments is provided in the claims as originally filed and at paragraph 21 of the specification. Reconsideration of the rejected claims is respectfully requested in view of the above amendments and the following remarks.

#### ***Allowed Claims***

Applicant appreciates the indication that claims 2-6, 8, 10-12, 14, and 20-22 contain allowable subject matter. However, Applicant submits that all of the claims are in condition for allowance for the following reasons.

#### ***Acknowledgment of Priority***

Applicant notes with appreciation the Examiner's acknowledgment of the claim of foreign priority and the receipt of certified copies of the priority documents.

#### ***Information Disclosure Statement***

Applicant would like to express appreciation to the Examiner for acknowledgment of Applicant's Information Disclosure Statement by the return of the initialed PTO-1449 forms.

#### ***Next Action Cannot Be Made Final***

Applicants note that although the Examiner refers (at the bottom of page 5 of the Office Action) to the rejection of claim 4, no reasons therefore were set forth in the Office Action. Thus, any future rejection of claim 4, as well as claims 11 and 21 as referred to in the Office Action, cannot be made final without a First Action rejection.

Serial No.: 10/825,183

***Objection to Drawing***

The Examiner objected to the drawings and asserted that the components need to be labeled instead of numbered. Applicants traverse the objection, and note that numerals are preferred for use as reference characters. (37 C.F.R. § 1.84(p)(1) and MPEP § 608.02(p)(1).) Moreover, as the “components” of the drawings are not large enough to accommodate labels that would remain legible when the patent is printed, Applicants have maintained the use of numerals as reference characters in the drawing, and respectfully request withdrawal of the objection.

***Claim Objections***

Claim 1 was objected to based upon use of the term “whether or not” in the preamble. Claims 1 and 26 have been amended to address the Examiner’s concern. Therefore, Applicants respectfully request withdrawal of the objection to claim 1.

Additionally, the Examiner objected to claim 3 based upon the use of the term “operating theater,” and suggested replacement with the term “operating room.” Applicants respectfully traverse the objection, and note that the use of this claim term is supported in the specification at paragraphs [0008] and [0022]. Moreover, Applicants note the term “operating theater,” as well as the scope of claim 3, would be readily understood by one of skill in the art reviewing the specification and the claims. Therefore, Applicants respectfully request withdrawal of the objection to claim 3.

***35 U.S.C. § 103(a) Rejection***

Claims 1, 3, 7, 9, 13, 15-18, 19, and 24-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application No. 2002/0143320 issued to Levin (hereinafter, “LEVIN”) in view of U.S. Patent No. 5,969,606 issued to Reber et al. (hereinafter, “REBER”). These rejections are respectfully traversed.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. To establish a *prima facie* case of obviousness, three basic

Serial No.: 10/825,183

criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2142.

The Examiner asserts that the applied prior art teaches or suggests all of the features of the claimed invention. Applicants respectfully disagree and submit that the Examiner has failed to establish a *prima facie* case of obviousness.

Independent Claim 1

Claim 1 recites, in relevant part:

defining a maximum allowed time dT for being kept outside a controlled-atmosphere enclosure; and  
allowing the blood bag to be *requaified* when it is returned to the enclosure when both the time dT and the expiration date have not expired, and for the blood bag to be *dequaified* when one of the time dT and the expiration date have expired.

With regard to claim 1, the Examiner asserts that LEVIN teaches each and every limitation of claim 1, with the exception that LEVIN fails to teach “defining a maximum allowed time dT for being kept outside a controlled-atmosphere enclosure.” The Examiner asserts that REBER teaches this feature and that it would have been obvious to combine the teaching of LEVIN with REBER. First, Applicants respectfully disagree that LEVIN teaches the features of *defining a maximum allowed time*, *requaification*, and *dequaification*. Second, it is submitted that REBER does not compensate for these deficiencies in LEVIN. Third, Applicants respectfully disagree that it would have been obvious to combine the LEVIN and REBER references.

More specifically, the Examiner acknowledges that LEVIN fails to teach defining a maximum allowed time dT for being kept outside a controlled-atmosphere enclosure. The Examiner asserts, though, that REBER compensates for this deficiency. Applicants note that REBER discloses determining whether a time duration that a food item is

Serial No.: 10/825,183

outside of a storage place exceeds a predetermined threshold, and if so, indicating an alert. (REBER, col. 4, line 50 – col. 5, line 41.) Specifically, REBER discloses that the time duration can be determined from the difference between when the food item was removed from and returned to a storage place. (REBER, col. 5, lines 15-40.) That is, REBER does not teach indicating an alert when the *cumulative* time outside the storage place exceeds the threshold. For example, by the method disclosed in REBER, a food item (such as mayonnaise) may be kept outside of a storage place (such as a refrigerator) for ten minutes each day. But, even after twenty-five days of keeping mayonnaise outside of the refrigerator for ten minutes each day (cumulatively exceeding a predetermined threshold of two hours), REBER does not teach indicating an alert. Thus, REBER fails to teach or suggest defining dT for being kept outside a controlled environment, such that no proper combination of LEVIN and REBER can render obvious the present invention recited in at least independent claim 1.

In addition, the Examiner asserts that LEVIN teaches “allowing the blood bag to be requalified ... and dequalified ...” and cites to LEVIN, paragraphs [0072] and [0080]. While teaching that a device may “emit[ ] a signal when a certain date is reached,” (LEVIN, paragraph [0080]) LEVIN fails to teach or suggest *requalification of the blood bag when both the maximum time dT and the expiration date have not expired*. Moreover, Applicants note that REBER fails to teach or suggest the subject matter noted above as deficient in LEVIN, such that no proper combination of these documents can render obvious the present invention recited in at least independent claim 1.

Additionally, Applicants note that LEVIN relates to a method of tracking medical products, whereas REBER relates to a method for *monitoring a stored food item*. As such, one of ordinary skill in the art of blood transfusion would not look to the field of food storage (REBER) for solutions in LEVIN. Thus, with regard to LEVIN, Applicants submit that REBER is not analogous art. Therefore, it would not have been obvious to combine LEVIN and REBER in the manner asserted by the Examiner. Moreover, as the art is unrelated, the Examiner has identified no motivation in the art of record to even

Serial No.: 10/825,183

arguably suggest combining LEVIN and REBER. For all these reasons, no proper combination of LEVIN and REBER can even arguably render unpatentable the combination of features recited in claim 1.

Independent Claims 9, 19, and 26

While the Examiner asserts that claims 9, 19, and 26 correspond to claim 1, Applicants submit that claims 9, 19, and 26 recite different scopes of the invention than recited in independent claim 1.

Specifically, claim 9 recites, in relevant part:

- monitoring a maximum allowed time dT that a blood bag may be kept outside a controlled-atmosphere enclosure...;
- indicating whether the blood bag may be transfused to a patient when both the time dT and the expiration date have not expired; and
- indicating whether the blood bag may not be transfused to a patient when one of the time dT and the expiration date has expired.

And, claim 19 recites, in relevant part:

- monitoring a maximum allowed time dT that a blood bag may be kept outside a controlled-atmosphere enclosure...;
- indicating whether the blood bag may be transfused to a patient when the time dT and the expiration date have not expired.

Finally, claim 26 recites, in relevant part:

- ... defining a maximum allowed time dT that a blood bag may be kept outside a controlled-atmosphere enclosure; and
- when the blood bag has been removed from the controlled-atmosphere enclosure, one of *qualifying*, *requalifying*, or *dequalifying* the blood bag, wherein requalifying comprises determining when both the time dT and the expiration date have not expired, whereby the blood bag is returnable to the enclosure, and wherein dequalifying comprises determining that one of the time dT and the expiration date have expired, whereby the blood bag is to be destroyed.

As discussed above, LEVIN does not disclose defining a maximum allowed time dT for being kept outside a controlled-atmosphere enclosure. Additionally, as discussed above, LEVIN fails to disclose basing the status (requalified or dequalified), or the

Serial No.: 10/825,183

indication of that status, on the expiration of either or both of the maximum time dT and/or the expiration date. Moreover, for the reasons stated above, REBER does not compensate for the deficiencies of LEVIN noted above. Thus, Applicants submit that any proper combination of LEVIN and REBER would not teach all the features of at least claims 9, 19, and 26.

Dependent Claims 3, 7, 13, 15-18, 24-25, and 27-28

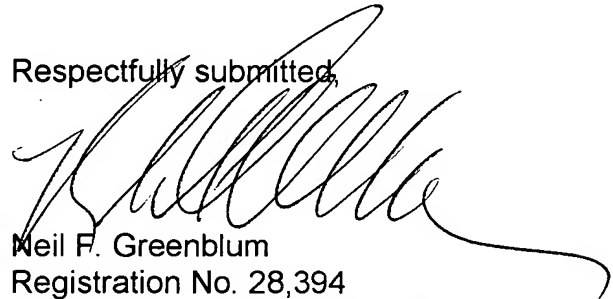
Claims 3, 7, 13, 15-18, 24-25, and 27-28 are dependent claims, depending from respective distinguishable base claims. Accordingly, these claims should also be in condition for allowance by virtue of their dependencies. Accordingly, Applicant respectfully requests that the rejections over claims 1, 3, 7, 9, 13, 15-19, and 24-28 be withdrawn.

Serial No.: 10/825,183

### CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that all of the claims are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue. The Examiner is invited to contact the undersigned at the telephone number listed below, if needed. Applicants hereby make a written conditional petition for extension of time, if required. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 19-0089.

Respectfully submitted,



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